

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 06 2004

In re the Application of:

Zernbower et al.

Filing Date: January 5, 2001

Serial No.: 09/755,779

For: USE OF AUTOMATED TECHNOLOGY IN  
CHEMICAL PROCESS RESEARCH AND  
DEVELOPMENT

Examiner Moran, Marjorie A

Group Art Unit 1631

OFFICIAL

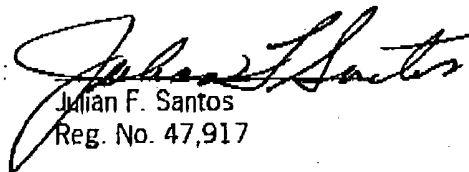
FACSIMILE TRANSMITTAL LETTERMail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450Attn: Marjorie A. Moran  
Fax: 703-872-9306Number of Pages: 5  
Including this Transmittal Letter

Sir:

In regard to the above identified application:

1. We are transmitting herewith the attached:
  - a) Response to Restriction Requirement mailed June 4, 2004.
2. With respect to additional fees:
  - a) Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490.
3. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described in paragraph 1 hereinabove, are being facsimile transmitted to the Patent and Trademark Office (Fax No. 703-872-9306) on this 6<sup>th</sup> day of July, 2004.

By:

  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RECEIVED  
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JUL 06 2004

**MBHB Case No. 99,321-A****OFFICIAL**

In re the Application of:

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Examiner Moran, Marjorie A

Group Art Unit 1631

Mail Stop Amendment  
Commissioner for Patents  
P.O. BOX 1450  
Alexandria, VA 22313-1450**RESPONSE TO THE RESTRICTION REQUIREMENT MAILED**

Dear Sir:

On June 4, 2004, the Office mailed an Office Action containing a Restriction Requirement that requires restriction of the present application into one of two groups, which the Examiner defined as follows:

- I. Claims 1-25, drawn to methods of optimizing crystallization of a target molecule, classified in class 702, subclass 27.
- II. Claims 26-32, drawn to a method for optimizing chiral resolution, classified in class 702, subclass 27.

In compliance with MPEP § 818, the Applicants elect Group I. However, the Applicants respectfully traverse this restriction requirement. A restriction requirement is only proper if the

application supports inventions that are either independent or distinct, and the search and examination of the entire application places a serious burden on the Examiner. See MPEP § 803.

The Applicants submit that the claims in Group I and Group II are not separate inventions despite the Examiner's contentions that the claims in Group I are drawn to methods of optimizing crystallization of a target molecule and the claims in Group II are drawn to a method for optimizing chiral resolution. The Examiner asserts that the claims in Group I and Group II are "different inventions [that] are directed to methods reciting different intended results and different method steps." The Applicants respectfully disagree with the Examiner, and submit that the claims in Group I and Group II are directed to embodiments of the same invention.

The claimed invention is directed to optimize the chemical process of crystallization by using automated technology. To facilitate this, the invention may use multiple steps to determine optimal conditions for a crystallization process. In one embodiment, the steps may include, for example, identifying variables which affect crystallization, choosing a finite number of experimental tests, wherein the experimental tests have values for the variables, providing a plurality of wells, assigning each of the experimental tests to a particular well, dispensing reagents and solvents into a plurality of wells chosen from the values for the experimental tests, crystallizing in the synthesizer using operating conditions chosen from the values for the experimental tests, analyzing crystals in the plurality of the wells, automatically generating a statistical analysis using the computer based on the analysis of the crystals in the plurality of the wells and at least one of the variables identified in order to evaluate the crystallization in the wells, and automatically generating, using the computer, suggested parameters for future experiments based on the statistical analysis.

In another embodiment, the steps may include, for example, identifying variables which affect chiral resolution, choosing a finite number of experimental tests, wherein the experimental tests have

values for the variables, providing a plurality of wells, assigning each of the experimental tests to a particular well, dispensing reagents and solvents into a plurality of wells chosen from the values for the experimental tests, crystallizing in the synthesizer using operating conditions chosen from the values for the experimental tests, obtaining at least a portion of contents from the plurality of wells, analyzing to determine the magnitude of chiral resolution for the at least a portion of the contents from the plurality of wells, automatically generating a statistical analysis using the computer based on the step of determining the magnitude of chiral resolution and at least one of the variables identified in order to evaluate the chiral resolution in the wells and automatically generating, using the computer, suggested parameters for future experiments based on the statistical analysis.

As can be readily discerned from the claims, the embodiments in Group I and Group II include similar method steps, in a similar order. One difference between the embodiments claimed in Group I and Group II is the type of crystallization process. Regardless of the type of crystallization process, however, the steps taken to determine optimal conditions for a crystallization process are similar.

Furthermore, the Applicants submit that due to the closely related nature of the claims in Group I and Group II, it would not place a serious burden on the Examiner to examine concurrently all the pending claims. Under MPEP § 803, if the search and examination of the entire application can be made without serious burden, "the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions."

As the Examiner noted in the Office Action, both the claims in Group I and the claims in Group II are classified in the same class (702) and the same subclass (27). The subclass is defined as "subject matter comprising means to determine structure of a sample on the molecular level or means to identify different components making up an unknown sample." Furthermore, both the claims in Group I and the claims in Group II are generally drawn to methods for optimizing a chemical

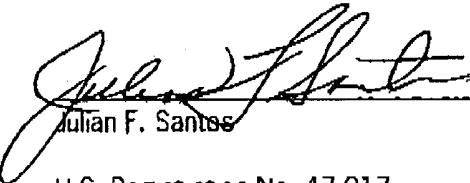
process. Accordingly, the Applicants submit that a search and examination of two groups of claims in the same class and subclass does not place a serious burden on the Examiner.

In light of the foregoing, the Applicants submit that the claims in the present invention are not directed to independent or distinct inventions, but instead, are directed to one common invention. Restriction of the claims into two groups by the Examiner therefore detracts from the consistency and unity of the invention. Accordingly, the Applicants respectfully submit that the restriction requirement is improper and request withdrawal of the restriction requirement. The Applicants further request prompt, favorable examination of the entire subject matter of the Groups I and II.

Respectfully submitted,

Date: July 6, 2004

By:



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